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JAO

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,107	10/30/2001	Grant L. Schoenhard	13726US01	8970
23446	7590	03/31/2005	EXAMINER	
MCANDREWS HELD & MALLOY, LTD 500 WEST MADISON STREET SUITE 3400 CHICAGO, IL 60661			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/000,107	SCHOENHARD, GRANT L.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 December 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 48-52,54 and 55 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 48-52 and 54-55 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Amendment Entry***

1. The amendment of December 17, 2004 has been entered. Claim 48 has been amended. Claim 53 has been cancelled. Claims 48-52 and 54-55 are under consideration in this office action.
2. A complete reply to the final rejection must include cancellation of nonelected claims, withdrawn claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Withdrawal of Rejections***

3. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:
  - a) the objection of the instant specification; and
  - b) the written description rejection of claims 48-55 under 35 U.S.C. 112.

***Response to Arguments***

4. Applicant's arguments filed December 17, 2004 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of claims 48-52 and 55 under 35 U.S.C. 103(a) as being unpatentable over Minoia et al., (US Patent 5,811,451) is maintained for the reasons already of record. The rejection was on the grounds that it was *prima facie* obvious to combine the opioid inhibitor of an ABC drug transporter; and an anti-microbial agent as taught by Minoia et al., into one composition since no more than routine skill would have been required to make said combination when the art already teaches that the components are useful for the same purpose of treating an animal with a microbial infection. Moreover, one skilled in the art would have a reasonable expectation of success when the two components are combined to create a single composition comprising components known to be used for the very same purpose and the prior art teaches those components as useable together and than no more than routine skill would have been required to combine such components.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to use the claimed opioid inhibitor of an ABC drug transporter; and an anti-microbial agent when they have been taught as useful together in an old process to achieve the expected and beneficial results found when using the separate compounds in a single composition. Moreover, there would have been a reasonable expectation of success since Minoia et al., already teach the combined use of opioid drugs for the treatment of several microbial pathologies.

Applicants' amendment drawn to the specific type of microbe causing the microbial infection does not add applicants' response. The argument that the claims require a specific type of microbe to cause the microbial infection does not result in a structural difference between the claimed composition and the prior art composition. This structural difference is necessary in order to patentably distinguish the claimed invention from the prior art. Moreover, the prior art opioid inhibitor of the ABC drug transporter is capable of inhibiting a drug transporter protein, thus it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Therefore the rejection is maintained since applicants' arguments are not found persuasive.

6. The rejection of claims 48-52 and 55 under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US Patent 4,466,968) is maintained for reasons already of

record. The rejection was on the grounds that no more than routine skill would have been required to combine the claimed opioid inhibitor of an ABC drug transporter; and the anti-microbial agent into a composition when each component has already been taught as useful together in an old process in order to achieve the expected and beneficial results found when using the separate compounds in a single composition.

Bernstein (US Patent 4,466,968) teaches the administration of naltrexone followed by the administration of the anti-microbial agents such as erythromycin and tetracycline. It is noted that the instant specification and claims define opioid inhibitors of the ABC drug transporters can be naltrexone or naloxone. Thus, the opioid inhibitors cited by Bernstein have the claimed compound formula and meet the qualifications as homologues of PGP1a.

Therefore in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it was *prima facie* obvious to combine the opioid inhibitor of an ABC drug transporter; and the anti-microbial agent taught by Bernstein since each component is taught to be useful for the same purpose of treating a microbial infection. No more than routine skill would have been required to form the claimed composition since each component is already well known in the art to be used for the very same purpose of microbial infection treatment; moreover, the idea of

combining them flows logically from their having been taught in the prior art as useable together.

As previously stated, the amendment drawn to requiring that a specific type of microbe to cause the microbial infection does not result in a structural difference between the claimed composition and the prior art composition. Thus a structural difference is necessary in order to patentably distinguish the claimed invention from the prior art. Therefore the rejection is maintained since there would have been a reasonable expectation of success since Bernstein already teaches the combined use of opioid drugs for the treatment of microbial infections and the prior art teaches a composition comprising the same components as those instantly recited.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 48-52 and 54-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 recites the limitation "wherein the microbe causing the microbial infection is..." in the claims. There is insufficient antecedent basis for this limitation in the claim. Moreover, it is unclear what microbe the

claim is referring to, since no microbes or treatment of microbial infection is recited by the instant claim. Thus. Clarification is required to overcome the rejection.

8. Claim 48 recites alternative limitations which are improperly expressed, see "...wherein the microbe causing the microbial infection is one of the groups of microbes that are..." Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
March 21, 2005

  
Lynette A. Smith  
US PATENT & TRADEMARK OFFICE  
U.S. DEPARTMENT OF COMMERCE